

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

In re: Effexor XR Antitrust Litigation

This document relates to:

All Actions

Lead case: 3:11-cv-05479-PGS-LHG (D.N.J.)

**DECLARATION OF A. LUKE SMITH IN SUPPORT OF PLAINTIFFS’  
MOTION TO TRANSFER, OR IN THE ALTERNATIVE, TO COMPEL**

I, A. Luke Smith, hereby declare as follows pursuant to 28 U.S.C. § 1746:

1. I am an attorney representing the direct purchaser class plaintiffs in *In re: Effexor XR Antitrust Litigation*, 11-cv-05479 (D.N.J.) (“Plaintiffs”).

2. On or about May 17, 2018, Plaintiffs served on Apotex Corp. (“Apotex”) a subpoena, dated May 16, 2018, to produce documents (the “Subpoena”). A true and correct copy of the Subpoena and proof of service is attached hereto as Exhibit A.

3. On or about May 24, 2018, Apotex’s counsel, Richard Ruzich (of Taft Stettinius & Hollister LLP) served Apotex’s Objections and Responses to the Subpoena, a true and correct copy of which is attached hereto as Exhibit B.

4. Thereafter, the parties participated in telephone meet and confers on June 19, June 26, July 11, August 1, September 5, September 10, October 2, October 17, October 24, October 31, and November 11, 2018.

5. Over the course of these meet and confers, Plaintiffs explained the relevance, and narrowed the scope, of the requests. Plaintiffs explained the relevance and need for Apotex to

produce its transaction-level sales data; documents concerning or produced in the underlying patent litigation; draft and final settlement and authorized generic license agreements with Wyeth, and documents concerning their negotiation; Apotex's Effexor XR Abbreviated New Drug Application ("ANDA") and related regulatory correspondence; forecasting documents; and documents concerning Apotex's manufacturing and launch preparation. Plaintiffs offered to accept specific narrowed topics in lieu of a full responsive production to all topics, waived altogether the request for manufacturing documents and regulatory correspondence on Apotex's ANDA, and ultimately agreements were reached with respect to several categories, as reflected in the true and accurate copy of an email thread with Apotex's counsel, attached hereto as Exhibit C.

6. During the meet and confer, Apotex consented to Wyeth's production of trial exhibits from the Apotex patent litigation (which Plaintiffs accepted in lieu of Apotex producing all documents produced in the underlying Wyeth-Apotex generic Effexor XR patent litigation). In addition, Apotex agreed to, and did, produce:

- a) the Apotex Effexor XR ANDA (which was a trial exhibit in the underlying patent litigation, but not retained by Wyeth); and
- b) An executed final version of the Apotex's Effexor XR patent settlement/AG license agreement.

7. However, Apotex maintained its refusal to produce several important categories of requested documents, including:

- a) transaction-level sales data as described at Subpoena request numbers 13-15, which is relevant to calculate class-wide damages as described in my email dated October 22, 2018, attached hereto as Exhibit D;<sup>1</sup>

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<sup>1</sup> After extensive negotiation, Apotex did agree to produce "sales data," but what it ultimately produced was annual summary IMS data concerning Effexor XR sales. As detailed on meet and

- b) all unit and sales forecasts,<sup>2</sup> launch plans, or projections for the ANDA or AG product, including all assumptions used, and all related correspondence; and
- c) drafts of the settlement/AG license agreement and internal and external correspondence regarding the negotiation of same.

8. In addition to the lengthy negotiation regarding the scope of the requests, the meet and confer process was further extended by several issues, including obtaining and communicating Apotex's consent to Wyeth's production of trial exhibits in the underlying patent litigation and getting that production from Wyeth; and the logistics of Plaintiffs obtaining, scanning, Bates stamping, and reviewing the hard copy version of Apotex's ANDA, which had been used as a trial exhibit but not retained by Wyeth. In addition, Apotex initially agreed to produce the requested sales data and forecasts and eventually made a production that purportedly included these documents, but when Plaintiffs reviewed the production it was clear that Apotex had not produced the requested transaction-level sales data or the requested forecasting documents. Plaintiffs informed Apotex that its production was inadequate (*see* Exhibit D), and Plaintiffs and Apotex then engaged in another round of meet and confers that ultimately resulted in impasse on those categories of documents listed at paragraph 7, above.

9. The Apotex subpoena is one of sixteen similar subpoenas served by Plaintiffs in this matter on generic manufacturers that sought regulatory approval from the Food and Drug Administration to market generic Effexor XR. Enforcement courts of these sixteen subpoenas

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confers prior to this production, Plaintiffs and their experts require Apotex's transaction-level sales data in native format.

<sup>2</sup> Apotex produced two standalone pages purporting to be AG forecasting documents, without any accompanying metadata, cover documents, or explanation of underlying assumptions.

span eight districts. A true and accurate table summarizing these subpoenas, and the compliance district where each is pending, is attached hereto as Exhibit E.

10. Plaintiffs met and conferred with Apotex regarding the deficiencies underlying this motion to no avail.

11. Plaintiffs also sought Apotex's consent to transfer of this motion to the issuing court in the District of New Jersey, and Apotex refused. *See* Exhibit F.

I declare under the penalty of perjury that the foregoing is true and correct. Executed this 11th day of February, 2019, in Philadelphia, Pennsylvania.



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